

**510(K) Summary****DEC 05 2013**

**Submitter:** El.En. S.p.A.  
via Baldanzese, 17  
50041 Calenzano (FI), Italy

**Contact:** Paolo Peruzzi  
Regulatory Affairs Manager & Official Correspondent  
Phone: +39.055.8826807  
E-mail: standards@elen.it

**Date Summary Prepared:** December 05, 2013

**Device Trade Name:** Deka Synchro Repla:Y family of Laser Systems

**Common Name:** Medical Laser and pulsed Light system

**Classification Name:** Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology (GEX)

**Classification Number** 21 CFR 878.4810

**Equivalent Devices:** Candela GentleMAX family of laser systems (K122715);  
Deka Synchro FT (K103288).

**Device Description:** The Deka Synchro Repla:Y family of lasers is a platform which can be equipped with two separate solid state laser heads (755nm and 1064nm) and a pulsed light handpiece (FT handpiece).  
The two laser heads can only be activated separately and they deliver the laser output through the same single laser delivery system, consisting of a lens coupled user replaceable optical fiber with a wide range of interchangeable, quick release laser handpieces with electronic spot recognition.  
The FT handpiece delivers the pulsed light to the treatment area by means of a sapphire lightguide; it is provided with has an integrated skin cooling system and is equipped with five different emission spectra interchangeable filters.  
The system allows to switch from one of the three available sources to the other by pressing a key on touch panel.  
Handpiece activation is either by footswitch or fingerswitch.

**Intended Use:** 755mn laser:  
Temporary hair reduction.  
Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9, and 12 months after the

completion of a treatment regime. On all skin types (Fitzpatrick I – VI) including tanned skin.

Treatment of benign pigmented lesions.

Treatment of wrinkles.

Photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

1064nm laser:

Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The lasers are indicated on all Skin Types Fitzpatrick I-VI including tanned skin.

Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins.

Coagulation and hemostasis of soft tissue.

Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques.

The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Treatment of wrinkles.

Pulsed light FT handpiece:

Permanent hair reduction, photocoagulation of vascular lesions, photothermolysis of blood vessels, treatment of benign pigmented lesions.

Substantial equivalence discussion    The DEKA Synchro Repla:Y family of laser systems is substantially equivalent to the Candela Gentle MAX family of laser systems as regards the 755nm and 1064nm laser, with similar performances and technology.

Device Trade Name	DEKA Synchro Repla:Y family of laser systems	Predicate Device K122715 Candela GentleMAX family of laser systems
Laser Type	Alexandrite, Nd:YAG	Alexandrite, Nd:YAG
Wavelength	755 nm, 1064 nm	755 nm, 1064 nm
Max Fluence	600 J/cm <sup>2</sup>	600 J/cm <sup>2</sup>

Spot Sizes	2.5 to 20mm	1.5 to 18 mm
Pulse Duration	0.25 to 300 ms	0.25 to 300 ms
Pulse Rep Rate	up to 10 Hz	up to 10 Hz
Skin Cooling System	Yes, optional	Yes, optional

The DEKA Synchro Repla:Y family of laser systems is substantially equivalent to the DEKA Synchro FT as regards the Pulse Light handpiece, with identical performances and technology.

Device Trade Name	<b>DEKA Synchro Repla:Y family of laser systems</b>	Predicate Device <b>K103288 DEKA Synchro FT</b>
Device Type	Pulsed Flashlamp	Pulsed Flashlamp
Wavelengths (nm)	500 - 1200nm 520 - 1200nm 550 - 1200nm 600 - 1200nm 650 - 1200nm	500 - 1200nm 520 - 1200nm 550 - 1200nm 600 - 1200nm 650 - 1200nm
Pulse Width	3 – 124 ms	3 – 124 ms
Fluence	3 - 25 J/cm <sup>2</sup>	3 - 25 J/cm <sup>2</sup>
Repetition Rate	0.5 Hz max.	0.5 Hz max.
Spot Sizes	48x13 mm	48x13 mm
Method of Skin Cooling	Integrated - provided via the handpiece lightguide	Integrated - provided via the handpiece lightguide
Method of Output	Direct Delivery Handpiece	Direct Delivery Handpiece

The DEKA Synchro Repla:Y family of laser systems has the same indications for use as the abovementioned predicate devices, with same principle of operation and essentially the same performances.

Clinical Performance Data:

None

Non-Clinical Performance Data:

Performance data has been provided in order to show that the Deka Synchro Repla:Y Software complies with the Requirements of the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued by the FDA on May 11, 2005.

Moreover, performance data has been provided in order to show that the Deka Synchro Repla:Y complies with the EMC

requirements of the FDA Recognized Standard IEC 60601-1-2 and with the FDA/CDRH Recommendations for EMC/EMI in Healthcare Facilities.

**Conclusion:**

The Deka Synchro Repla:Y family of laser systems is a family of safe and effective devices for the applications mentioned above.

**Additional Information:**

None



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

EL. EN Electronic Engineering SPA  
Paolo Peruzzi  
Regulatory Affairs Manager  
Via Baldanzese 17  
Calenzano, Florence 50041  
ITALY

December 5, 2013

Re: K131095

Trade/Device Name: Deka Synchro Repla:Y family of laser systems  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: October 18, 2013  
Received: October 21, 2013

Dear Peruzzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joshua C. Nipper -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(K) Number (if known): K131095

Device Name: Deka Synchro Repla:Y family of laser systems

### Indications For Use:

The DEKA Synchro Repla:Y family of laser systems is indicated for:

#### 755nm laser:

Temporary hair reduction.

Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles.

Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

On all skin types (Fitzpatrick I – VI) including tanned skin.

Treatment of benign pigmented lesions.

Treatment of wrinkles.

Photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

Prescription Use ☒ X

AND/OR

Over-The-Counter Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Neil R Ogden

2013.12.04 15:44:31 -05'00'

(Division Sign-Off) For BSA

Division of Surgical Devices

510(k) Number K131095

1064nm laser:

Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB . The lasers are indicated on all Skin Types Fitzpatrick I-VI including tanned skin.

Photocoagulation and hemostasis of pigmented and vascular lesions, such as but not limited to port wine stains, hemangioma, warts, teleangiectasia, rosacea, venus lake, leg veins and spider veins.

Coagulation and hemostasis of soft tissue.

Benign pigmented lesions such as, but not limited to, lentigos, (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratosis, nevi, cloasma, verrucae, skin tags, keratosis and plaques.

The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Treatment of wrinkles.

Prescription Use ☒ X

AND/OR

Over-The-Counter Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of Center for Devices and Radiological Health (CDRH)

Neil R Ogden

2013.12.04 15:44:53 -05'00'

(Division Sign-Off) For BSA

Division of Surgical Devices

510(k) Number K131095



**Pulsed light FT handpiece:**

Permanent hair reduction, photocoagulation of vascular lesions, photothermolysis of blood vessels, treatment of benign pigmented lesions.

Different wavelength ranges of Pulsed Light attachment are indicated for the various treatments and skin types, as indicated in the following table:

Pulsed light wavelength range	Hair reduction	Vascular lesions	Blood vessels	Pigmented lesions
500 - 1200nm	-	Skin Types I, II	Skin Types I, II	-
520 - 1200nm	-	Skin Type III	Skin Type III	Skin Types I, II
550 - 1200nm	Skin Types I, II	-	-	Skin Type III
600 - 1200nm	Skin Type III	-	-	-
650 - 1200nm	Skin Type IV	-	-	Skin Type IV

Prescription Use ☒ X

AND/OR

Over-The-Counter Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Neil R Ogden

2013.12.04 15:45:12 -05'00'

(Division Sign-Off) For BSA

Division of Surgical Devices

510(k) Number K131095